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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,240	07/21/2004	Sadao Omata	IS14-002	3991

7590 10/05/2006

EXAMINER
ROGERS, KRISTIN D

ART UNIT	PAPER NUMBER
3736	

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DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/502,240	OMATA, SADAO	
	Examiner	Art Unit	
	Kristin D. Rogers	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 6, 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 8-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 8-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, claim 13 includes introduction of a new limitation regarding the cross section of the probe base. The specification lacks support for the embodiment of a probe base having a square cross section.

3. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, claim 18 includes subject matter pertaining to the elongated structure of the probe base and the resilient arm member extending at an angle relative the longitudinal axis at an angle being less than 88 degrees. The specification lacks support for this embodiment.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonard et al. (6063044). In regard to claim 1, Leonard et al. shows an elasticity measuring device **20**, a probe base **23**, at least one probe comprising the upper, internal, and lower housings, 42,60, and 29 respectively, arranged around the probe base, a resilient arm member **68** which comprises spring member **66**, a stress detection sensor **58** that is secured to the probe (Column 5, lines 50-55), and a deviation detection sensor **55,56,** wherein the elasticity of the biological tissue is measured based on the stress and deviation magnitude when the probe is pressed onto and return from the tissue. In regard to claim 4, Leonard et al. shows a stress detection sensor **58** comprising of a distortion gauge.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 2, 8-9,11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. as applied to claim 1 above and in view of Arhan et al. (4566465). Leonard et al. shows an elasticity measuring device **20**, a probe base **23**, at least one probe arranged around the probe base, a resilient arm member **68**, a stress

detection sensor **58**, and a deviation detection sensor **55,56**. Regarding claim 2, Leonard et al. lacks a resilient arm member comprising a plurality of spring members and a plurality of probes. Arhan et al. teaches a probe for measuring visco-elastic behavior of sphincters that comprises of a probe **Figure 1**, a probe base **18**, resilient arm member **7** comprising a plurality of spring members **5,6**, and a plurality of probes **1,2,3**, for the purpose of arranging the probes symmetrically around the probe base. The spring members 5 and 6 are considered equivalent structures and are capable of providing the function of expanding and retracting the plurality of probes. Regarding claim 8, Leonard shows a probe base that lacks the structural configuration of an elongated bar. Arhan et al. teaches a probe base 10 comprising an elongated bar (Figure 1) for inserting into the inner canal of the human body. Regarding claim 9, Leonard shows a probe that is capable of movement in the longitudinal direction, but lacks teaching a probe configured to move perpendicularly to the outer surface of the probe base. Arhan et al. teaches a probe base 10 with outer surface wherein at least one probe 1,2,or 3 is configured to expand and retract perpendicularly to the outer surface of the probe base (See Figure 1) for providing means to contact tissue. Regarding claim 11, Leonard teaches a probe that is configured to move in a longitudinal axial direction, but lacks teaching a cooperating sleeve. Arhan et al. teaches probe base 10 and sleeve members 8,9 which surround probe base 10 and move apart from or towards each other as the probe moves in the perpendicular direction (column 3, lines 4-16) for contacting the inner canal of the body. Regarding claim 12, Leonard shows a probe and probe base that is capable of movement in the

longitudinal direction, but lacks teaching a probe base comprising an elongated structure extending the longitudinal axis wherein at least one probe is configured to move perpendicularly to the longitudinal axis. Arhan et al. teaches a probe base 10 comprising an elongated structure extending a longitudinal axis wherein at least one probe 1,2,or 3 is configured to expand and retract perpendicularly to the longitudinal axis (See Figure 1) for providing means to contact tissue. Regarding claim 13, Leonard shows an elasticity measuring device comprising a probe base, but lacks disclosure regarding the shape of the cross section. Arhan et al. teaches a probe base having a circular cross section (column 1, lines 35-36, Figure 2) for ease of insertion into a sphincter canal, but does not expressly disclose a probe base having a square cross section. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the probe base of Arhan et al. to have a square cross section because Applicant has not disclosed that a square cross section provides and advantage, is used for a particular purpose, or solves a stated problem. One of Ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a probe base having a circular cross section because a circular cross section would provide smooth edges for insertion into a canal part of the body without damaging surrounding tissue. Regarding claim 14, Leonard shows a probe base, probe and a resilient arm member, but does not disclose that the probe is in a fixed relation relative the resilient arm member. Arhan et al. teaches at least one probe 1,2 or 3 in a fixed relation relative the resilient arm member 7, (Figures 1 and 2) for providing a stable support for contacting the inner canal

of the body. Regarding claim 15, Leonard et al. shows a probe and resilient arm member, but lacks teaching the probe being affixed to the resilient arm. Arhan et al. teaches at least one probe 1,2 or 3, affixed to the resilient arm member 7 (Figure 1) for contacting the tissue to measure elasticity. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the device of Leonard et al. with a resilient arm member comprising a plurality of springs and a plurality of probes, a probe base configured as an elongated bar having a circular cross section, probe members affixed to the resilient arm member and configured to move perpendicularly from the probe base, a sleeve, and probe base comprising an elongated structure as taught by Arhan et al. for the purpose of providing a symmetrical arrangement of probes around the probe base in which to contact tissue in the inner canal of the body.

8. Claims 3 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. in view of Huszar (4432376). Leonard et al. shows an elasticity measuring device 20, including a resilient arm member 68, and deviation detection sensors 55 and 56, but lacks teaching a deviation detection sensor comprising a pair of light emitting and light receiving elements, affixed to the resilient arm members. Regarding claim 3, Huszar teaches a deviation detection sensor comprising a pair of light emitting element and light receiving element, said light emitting element being secured on a surface of said probe base 22 and 32 and said light receiving element being secured on said spring member 38 and 28 so as to oppose to each other (Figure 11, 12 and 13, column 7, lines 43-49) for measuring the distance between the stress

detection sensor. Regarding claim 17, Huszar teaches an elasticity measuring device comprising resilient arm members 28 and 38 in which a deviation detection sensor 50 is affixed for measuring the distance between the stress detection sensor 42, 44, and 60. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Leonard et al. with deviation detection sensors affixed to the resilient arm member as taught by Huszar since such modification would provide a means to measure the displacement between the stress detection sensor.

9. Claims 10,16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leonard et al. in view of Imran (5396887). Regarding claim 10, Leonard et al. shows an elasticity measuring device 20, including a resilient arm member 68, but lacks teaching a resilient arm member that comprises a plate spring. Imran teaches an apparatus for detecting contact pressure including a probe base 11, resilient arm members comprising a plate spring 17. Resilient arms 17 are flexible extending arms which have an outwardly bowed shaped memory for expanding the probe assembly to engage the inner canal of the body (Column 2 lines 24-29 Figure 1). Regarding claim 16, Leonard et al. shows an elasticity measuring device 20, a resilient arm member 68 and a stress detection sensor 58, but lacks teaching the stress detection sensor being affixed to the resilient arm member. Imran teaches pressure/stress detection sensors 27 affixed to the resilient arm members 17 shown in Figure 1 for measuring contact pressure. Regarding claim 18, Leonard et al. shows an elasticity measuring device 20, a probe base 23 and resilient arm member 68, but lacks teaching the resilient arm member extending at an angle less than 88 degrees relative to the longitudinal axis.

Imran teaches resilient arm members 17 that extend from the probe base 11 at an angle relative to the longitudinal axis at an angle being less than 88 degrees, as shown in Figure 1, for contacting the inner canal of the body. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Leonard et al. with a resilient arm member comprising a plate spring, a stress detection sensor affixed to the resilient arm member, and a resilient arm member extending at an angle less than 88 degrees relative to the longitudinal axis of the probe base as taught by Imran for the purpose of providing a contact means for measuring the elasticity of the inner canal of the body.

Response to Arguments

10. Applicant's arguments with respect to claims 1-4 and 8-18 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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